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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICEApplicants: Soderlund *et al.*

Examiner: Unassigned

Serial No.: 09/258,216

Group Art Unit: 1634

Filed: February 26, 1999

Docket: 13025-5

For: METHOD AND REAGENT FOR DETERMINING
SPECIFIC NUCLEOTIDE VARIATIONSKalow & Springut LLP
488 Madison Avenue, 19th Floor
New York, New York 10022

June 15, 2000

Assistant Commissioner for Patents
Washington, D.C. 20231**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicants submit herewith the following disclosures in accordance with the provisions of 37 CFR § 1.97 and § 1.98.

US PATENT DOCUMENTS

| <u>PATENT NO.</u> | <u>TITLE</u> | <u>ISSUE DATE</u> |
|--|--|--------------------------|
| 4,307,189 to Kit | Method for the Quantitative Determination of Terminal Deoxynucleotidyl Transferase in Biological Samples | December 22, 1981 |
| 4,563,419 to Ranki <i>et al.</i> | Detection of Microbial Nucleic Acids By a One-Step Sandwich Hybridization Test | January 7, 1986 |
| 4,683,195 to Mullis <i>et al.</i> | Process for Amplifying, Detecting and/or Cloning Nucleic Acid Sequences | July 28, 1987 |
| 4,883,750 to Whiteley <i>et al.</i> | Detection of Specific Sequences in Nucleic Acids | November 28, 1989 |

*These references are not enclosed as they were provided in parent application 08/162,376 and are already of record. (37 CFR §1.98(d)).

Certificate of Mailing Under 37 C.F.R. 1.8

I hereby declare that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, DC 20231

15 June 2000
DateNathaniel Brand
Name

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| <u>PATENT NO.</u> | <u>TITLE</u> | <u>ISSUE DATE</u> |
|-------------------------------------|---|-------------------|
| 4,962,020 to Tabor <i>et al.</i> | DNA Sequencing | October 9, 1990 |
| 4,968,602 to Dattagupta | Solution-Phase Single Hybridization Assay For Detecting Polynucleotide Sequences | November 6, 1990 |

FOREIGN PATENT DOCUMENTS

| <u>DOCUMENT NO.</u> | <u>TITLE</u> | <u>PUBLICATION DATE</u> |
|---------------------|--|-----------------------------|
| GB 2,202,328 | An Improved Method for Assaying of Nucleic Acids, a Reagent Combination and a Kit Therefore | 21 September 1988 |
| WO 86/03782 | Improved Sandwich Hybridisation Technique for the Detection of Nucleotide Sequences | 3 July 1986 |
| WO 89/09282 | Method of Sequencing DNA | 5 October 1989 |
| WO 89/10414 | Amplified Sequence Polymorphisms (ASPs) | 2 November 1989 |
| WO 90/01069 | Process for Amplifying and Detecting Nucleic Acid Sequences | 8 February 1990 |
| WO 90/06042 | Detection and Quantitative Determination of RNA and DNA | 14 June 1990 |
| *WO 90/11372 | Multiplex DNA Diagnostic Test | 4 October 1990 |
| EP 0238332 | Liquid Hybridization Method and Kit for Detecting the Presence of Nucleic Acid Sequences in Samples | 23 September 1987 |
| EP 0246864 | Hybridisation Probes | 25 November 1987 |
| EP 0288737 | Rapid Hybridization Assay Using Latex-Immobilized Probes | 2 November 1988 |

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| <u>DOCUMENT NO.</u> | <u>TITLE</u> | <u>PUBLICATION DATE</u> |
|---------------------|---|-------------------------|
| EP 0297379 | Assay of Sequences Using Amplified Genes | 4 January 1989 |
| EP 0317074 | Hybridization Method and Reagent Kit Therefor | 24 May 1989 |
| EP 0332435 | Method of Detecting Nucleotide Sequences | 13 September 1989 |
| EP 0333465 | Mutation Detection by Competitive Oligonucleotide Priming | 20 September 1989 |
| EP 0357011 | Detection and Amplification of Target Nucleic Acid Sequences | 7 March 1990 |
| EP 0370694 | Diagnostic Kit and Method Using a Solis Phase Capture Means for Detecting Nucleic Acids | 30 May 1990 |
| EP 0371437 | Method and Reagent Combination for Determining Nucleotide Sequences | 6 June 1990 |
| *EP 0412883 | Fast Process for Detecting and/or Identifying a Single Base on a Nucleic Acid Sequence and Its Applications | 13 February 1991 |

OTHER DOCUMENTS

1. Syvanen et al., "Direct Sequence of Affinity-Captured Amplified Human DNA Application to the Detection of Apolipoprotein E Polymorphism", FEBS Letters, 258:71-74 (1989).

2. Syvanen et al., "Quantification of Polymerase Chain Reaction Products by Affinity-Based
- *These references are not enclosed as they were provided in parent application 08/162,376 and are already of record. (37 CFR §1.98(d)).

- Hybrid Collection," Nucleic Acids Research, 16:11327-11339 (1988).
3. Ballabio et al., "PCR Test for Cystic Fibrosis Deletion", Nature, 343:220 (1990).
 4. Grimberg et al., "A Simple and Efficient Non-Organic Procedure for the Isolation of Genomic DNA From Blood", Nucleic Acids Research, 17:8390 (1989).
 5. Signer et al., "DNA Fingerprinting: Improved DNA Extraction From Small Blood Samples", Nucleic Acids Research, 16:7738 (1988).
 6. Signer et al., "Modified Gel Electrophoresis for Higher Resolution of DNA Fingerprints", Nucleic Acids Research, 16:7739 (1988).
 7. Mitchell et al., "Affinity Generation of Single Stranded DNA Following the Polymerase Chain Reaction: Application to Dideoxy Sequencing", WH 214 Journal of Cellular Biochemistry Supp. 13E 18th Annual Meeting (1989).
 8. Smith, "DNA Sequence Analysis by Primed Synthesis", Methods in Enzymology, 65:560-581 (1980).
 9. Kuppuswamy et al., "A New Use of Polymerase Chain Reaction (PCR) in Carrier Detection of Hemophilia-B Due to Point Mutations", Blood, The Journal of the American Society of Hematology, Thirty-First Annual Meeting of the American Society of Hematology, 74:957 (1989).
 10. Rommens et al., "Identification of the Cystic Fibrosis Gene: Chromosome Walking and Jumping", Science, 245:1059-1065 (1989).
 11. Riordan et al., "Identification of the Cystic Fibrosis Gene: Cloning and Characterization of Complementary DNA", Science, 245:1066-1072 (1989).
 12. Wu et al., "Allele-specific Enzymatic Amplification of β -Globin Genomic DNA for Diagnosis of Sickle Cell Anemia", Proc. Natl. Acad. Sci. USA, 86:2757-2760 (1989).
 13. Newton et al., "Analysis of Any Point Mutation in DNA. The Amplification Refractory Mutation System (ARMS)", Nucleic Acids Research, 17:2503-2516 (1989).

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14. Ehlen et al., "Detection of Ras Point Mutations by Polymerase Chain Reaction Using Mutation-Specific Inosine-Containing Oligonucleotide Primers", *Biochemical and Biophysical Research Communications*, 160: 441-447 (1989).
15. Nassal et al., "PCR-Based Site-Directed Mutagenesis Using Primers With Mismatched 3' - Ends", *Nucleic Acids Research*, 18:3077-3078 (1990).
16. Caskey et al., "Disease Diagnosis by Recombinant DNA Methods", *Science*, 236:1223-1228 (1987).
17. Landegren et al., "DNA Diagnostics - Molecular Techniques and Automation", *Science*, 242:229-237 (1988).
18. Rossiter et al., "Molecular Scanning Methods of Mutation Detection", *The Journal of Biological Chemistry*, 265:12753-12756 (1990).
19. Spitzer et al., "Replacement of Isoleucine-397 by Threonine in the Clotting Proteinase Factor IXa (Los Angeles and Long Beach Variants) Affects Macromolecular Catalysis but not L-tosylarginine Methyl Ester Hydrolysis", *Biochem. J.* 265: 219-225 (1990).
20. Kuppuswamy et al., "Single Nucleotide Primer Extension to Detect Genetic Diseases: Experimental Application to Hemophilia B (factor IX) and Cystic Fibrosis Genes", *Proc. Natl. Acad. Sci. USA*, 88:1143-1147 (1991).
21. Prober et al., "A System for Rapid DNA Sequencing With Fluorescent Chain-Terminating Dideoxynucleotides", *Science*, 238:336-341 (1987).
22. Landegren et al., "A Ligase-Mediated Gene Detection Technique", *Science*, 241:1077-1080 (1988).
23. Syvanen et al., "Direct Sequencing of Affinity-Captured Amplified Human DNA Application to the Detection of Apolipoprotein E Polymorphism", *FEBS Letters*, 258:71-74 (1989).
24. Mikita et al., "Functional Consequences of the Arabinosylcytosine Structural Lesion in DNA", *Biochemistry*, 27:4698-4705 (1988).
25. Wu et al., "Allele-Specific Enzymatic Amplification of β -Globin Genomic DNA for Diagnosis of Sickle Cell Anemia", *Proc. Natl. Acad. Sci. USA*, 86:2757-2760 (1989).
26. Mullis et al., "Specific Synthesis of DNA in Vitro Via a Polymerase-Catalyzed Chain Reaction", *Methods in Enzymology*, 155:335-351 (1987).

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27. Spitzer et al., "Molecular Defect in Factor IX_{Bm Lake Elsinore}", The Journal of Biological Chemistry, 263:10545-10548 (1988).
28. Ware et al., "Genetic Defect Responsible for the Dysfunctional Protein: Factor IX_{Long Beach}", Blood, 72:820-822 (1988).

The above documents are also listed on Applicants' PTO 1449 Form which is enclosed for the convenience of the Examiner. A copy of each of the items identified above which does not have an asterisk is submitted with this statement.

The attorneys for the Applicants take no position on whether or not any item cited above and listed on Form PTO 1449 constitutes prior art against the subject application under any particular provision of Title 35 of the United States Code.

If there are any questions or comments relating to the present application, the Examiner is respectfully invited to contact Applicants' attorney at the telephone number set forth below.

Respectfully submitted,



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